

P1 (d) one or more emulsifiers selected from the group consisting of a nonionic surface active agent and a trivalent cationic emulsifier and present in a total amount of about 2 percent to about 14 percent by weight based on the total weight of said formulation;

B P1 said water phase comprising water in an amount of about 45 percent to about 85 percent by weight based on the total weight of said formulation.

C' cont B B 37. A formulation according to Claim 36 wherein said isostearic acid is present in an amount of about 5 percent to about 25 percent by weight based on the total weight of said formulation.

B 38. A formulation according to Claim 34 in the form of an ointment comprising:

P1 B 39 (a) said 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine;

B P1 (b) said isostearic acid in an amount of about 3 percent to about 25 percent by weight based on the total weight of said formulation; and

P1 (c) a pharmaceutically acceptable ointment base in an amount of about 60 percent to about 95 percent by weight based on the total weight of said formulation.

Amend Claim 7 by replacing the numeral "6" in the first line of the claim by --36--. Amend Claims 9-13 by replacing the numeral "8" in the first line of these claims with --37--. Amend Claims 32 and 33 by replacing the numeral "1" in line 1 of the claim by --34--.

Remarks

Claims 2-4 and 15 are cancelled. Claims 1, 5, 6, 8, and 14 are also cancelled but are rewritten as described below in connection with new Claims 34-38. Claims 7, 9-13, and 32-38 are presented for consideration.

Claim 34 represents cancelled Claim 1 amended to replace the numerical limitation on the amount of the active ingredient with a functional recitation. This amendment finds support at page 5, lines 29-34 of the specification. While the literal terminology used in the claim does not appear in the specification, the concept expressed by the terminology is clearly present in the original specification. The amendment therefore does not introduce new matter to the specification. In re Anderson 176 USPQ 331 (CCPA 1973). Further, Applicants point out that functional terms such as that used in the claim have been deemed to be in compliance with 35 USC 112, second paragraph. In re Halleck 164 USPQ 647 (CCPA 1970), In re Caldwell 138 USPQ 243 (CCPA 1963). Claim 34 also deletes the recitation of oleic acid. This amendment finds support, e.g., in cancelled Claim 2.

Claim 35 represents cancelled Claim 5 amended to replace the numerical limitation on the amount of active ingredient with the numerical limitation found in original Claim 1.

Claim 36 represents cancelled Claim 6 amended to conform to Claim 34 and to eliminate component (e) from the claim. This amendment finds support, e.g., at page 6 lines 31-33, where the thickener is said to be an optional component of a creme formulation of the invention.

Claims 37 and 38 represent cancelled Claims 8 and 14 amended to conform to the new claims from which they depend.

Claims 7, 9-13, and 31-32 are amended to depend from new claims.

Applicants respectfully request entry of the amendments.

Turning now to the Office Action, the Examiner has issued a final rejection under 35 USC 103. At pages 2-3 of the Office Action, the Examiner states that the Affidavit of Stephen Berge demonstrates unexpected results in connection with isostearic acid but not in connection with oleic acid. The claims have been amended such that

they read only on those compositions that contain isostearic acid; that is, they read only on those compositions for which the Examiner admits unexpected results have been demonstrated. Accordingly, the amendment obviates the rejection.

The Examiner asserts that the demonstration of unexpected results pertains to the unobviousness of the method in which the claimed composition is used and not to the unobviousness of the compositions themselves. Applicants do not agree. As the Examiner is aware, it is well established that a compound and its properties are inseparable. In re Papesch 137 USPQ 43 (CCPA 1963). It follows that a case of prima facie obviousness of a chemical compound or other chemical composition can be overcome (and unobviousness of the compound or composition therefore established) by showing that the compound or composition possesses unobvious properties.

In Papesch the examiner had contended that a showing by applicant of a compound's unexpectedly advantageous antiinflammatory activity was relevant to the patentability of a method of use of the compound as an antiinflammatory agent and not to the patentability of the compound itself. Papesch, at 45. Neither the Board nor the court considered the examiner's contention sound, and indeed the court expressly discredited the examiner's position. Papesch, at 52. The result in Papesch was that claims to compounds per se were deemed patentable by virtue of their unexpected properties. The analogous result is appropriate here.

As for the method Claims 32 and 33, the Examiner asserts that these claims are not limited to transdermal administration nor to isostearic acid. As for isostearic acid, the amendment above obviates the Examiner's concern. As for the fact that the method claims recite, e.g., an antiviral effect, it is important to note that the argument above establishes patentability of the compositions involved in the claimed methods. The method Claims 32 and 33 contain limitations in addition to those found in the

composition claims, thus rendering these claims even further removed from the references applied by the Examiner. Applicants realize that patentability of the composition does not necessarily entitle them to the method claims; rather these claims must be judged by applying the facts to the statutory standards of obviousness. However, the Examiner's apparent contention that Applicant must show unexpected results in the claimed method has been expressly discredited in In re Kuehl 177 USPQ 250 (CCPA 1973).

For the reasons set forth above, Applicants respectfully request reconsideration, withdrawal of the rejection, and allowance of Claims 7, 9-13, and 32-38. Further, as all nonelected claims have been cancelled, Applicants contend that this case is in condition for allowance.

Please charge any additional fee due in connection with this paper to Deposit Account Number 13-3723.

Respectfully submitted,

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Date

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